filing a timely continuation or divisional application, based thereon. Claims 1, 3, and 15 have been amended for editorial purposes and to more clearly point out the presently claimed invention. No new matter has been added by these amendments.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1 to 8 and 15 to 21 under 35 U.S.C. § 112, first paragraph, as allegedly not providing enablement for the prevention for any autoimmune disease using any *Coxiella* antigen or an analogue or homologue thereof. The Examiner does note that the specification does enable inhibiting the occurrence of IDDM in a mammal, preventing the recurrence of IDDM in a spontaneously diabetic mammal transplanted with a syngeneic islet tissue, ameliorating the effects of IDDM and protecting beta cells from autoimmune destruction in a mammal comprising *Coxiella burnetii* QVAX vaccine or QFA antigen.

Applicants respectfully traverse this ground of rejection. As an initial matter, Applicants wish to thank the Examiner for noting the enablement of inhibiting the occurrence of IDDM in a mammal, preventing the recurrence of IDDM in a spontaneously diabetic mammal transplanted with a syngeneic islet tissue, ameliorating the effects of IDDM and protecting beta cells from autoimmune destruction in a mammal comprising *Coxiella burnetii* QVAX vaccine or QFA antigen. While Applicants disagree with the Examiner's general assertions regarding lack of enablement, solely in order to expedite prosecution, Applicants have amended the presently pending independent claims to the particular species, *i.e.*, *C. burnetii* and to one or more antigenic components therefrom. The broader scope of the claims will be prosecuted in a timely filed continuation application. With respect to the presently pending claim set, the specification provides examples of two antigens from *C. burnetii, i.e.*, Q-fever complement fixing antigen phase 1 (QFA) as well as QVAX, which is a Q-fever vaccine. Both of these are publicly available from CSL Limited, Melbourne Australia. At page 6, lines 12 *et seq,* the specification clearly supports the use of a killed preparation of a *C. burnetii* such as a heat killed or formalin killed preparation. Further, other antigen components of *C. burnetii* are described at page 6, line 20 *et seq* and include a lysed preparation of the whole organism, a membrane/wall preparation, an endospore preparation and one or more purified or partially purified antigenic molecules therefrom. Given that the examples clearly enable the skilled artisan to rapidly verify any

component from *C. burnetii* as antigenic, Applicants respectfully submit that the present specification is enabling for *C. burnetii* or any antigen therefrom.

With respect to the Examiner's contention that Applicants have not enabled treatment of any autoimmune disease, Applicants respectfully disagree. For enablement purposes, a specification need not teach what is well known in the art. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Moreover, some amount of experimentation is not fatal as long as the amount is not undue. *Id.* For the present claims, no undue experimentation is required, because the specification provides sufficient guidance to *allow* one of ordinary skill in the art to identify antigenic components of *C. burnetii*. Further these components can then be utilized in a variety of models to verify the activity. To the extent that the Examiner questions the utility or breadth of the claim set of the present invention, Applicants wish to point out that an assertion of utility and/or enablement within a disclosure is presumed to be correct. In order to challenge this presumption, the Examiner bears the initial burden of providing evidence showing that a person of ordinary skill in the art would reasonably doubt the disclosure. *In re Brana,* 34 U.S.P.Q. 2d 1436, 1441 (Fed. Cir. 1995). In the absence of such evidence, Applicants are not required to provide further evidence of the asserted utility or enablement, and a claim that corresponds in scope to the disclosure of the specification must be taken to satisfy the requirements of 35 U.S.C. §112, first paragraph. *Id.; in re Marzocchi,* 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). If the Examiner questions the asserted utility or enablement, then Applicants request that the Examiner provide support for this rejection, in the form of references or a declaration, in accordance with 37 C.F.R. § 1.107(b). On these bases, Applicants respectfully request that the Examiner withdraw this ground for rejection.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 1 to 8 and 15 to 21 under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and to distinctly claim the subject matter regarded as the invention. More specifically, the Examiner has indicated that claim 3 lacks proper antecedent basis for the term "the autoimmune condition" and claims 1 and 15 are vague in the recitation of the terms "analogous" or "homologous".

Applicants respectfully traverse these grounds for rejection in part. With respect to claim 3, Applicants wish to thank the Examiner for pointing out this informality in the claim. Accordingly, claim 3 has been amended to replace the term "autoimmune condition" with "autoimmune disease". With respect to the terms "analogous" and "homologous" in claims 1 and 15 Applicants respectfully submit that those of skill in the art would readily understand such terminology. However, solely in order to expedite prosecution, Applicants have deleted these terms from claims 1 and 15. Accordingly, the replacement of these terms obviates the rejection of dependent claims 2 to 8 and 16 to 21. Thus, Applicants respectfully submit that the aforementioned basis for rejection have been obviated and request that the Examiner withdraw the same.

Rejection under 35 U.S.C. §103(a)

The Examiner has alleged that claims 1 to 8 and 15 to 21 are obvious under 35 U.S.C. § 103(a) over Qin *et al.* in view of Vodkin, Edgington and Barnes *et al.*

Applicants respectfully traverse this ground for rejection. Applicants submit that the Examiner appears to be engaging in hindsight reconstruction in making these allegations. The Examiner is also engaging in unacceptable mosaicing of references from different art units. In particular, Qin *et al.* putatively teach a therapeutic composition comprising a suitable extract of *Mycobacterium* in a form of CFA. The Examiner has alleged that CFA is "analogous or homologous" to an antigenic component of *C. burnetii.* Given the cancellation of these terms, this reference is no longer applicable.

Vodkin *et al.* merely teach an immunogenic heat shock protein which is allegedly "homologous" to the component from *C. burnetii.* Again, given the amendments proposed above, this reference is no longer applicable.

Edgington and Barnes merely relate to the use of adjuvants. Applicants respectfully submit that contrary to the Examiner's allegation, it would not have been obvious to one of ordinary skill in the art to replace Qin's CFA with Vodkin's immunogenic *C. burnetii* HSP antigenic component.

Further Applicants wish to point out that specifically, in the biotechnology area, the Federal Circuit has enunciated three requirements for a *prima facie* obviousness rejection:

(1) the prior art must suggest the modification in the prior art process that is required for the invention, without reference to the specification of the applicant; (2) the reference must convey a reasonable expectation of success if the modification is made; and (3) the reference must be enabling for practicing the claimed invention. In addition, the analysis requires consideration of the prior art as a whole. (*see, e.g., In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986); *In re Bell,* 991 F.2d 781 (Fed. Cir. 1993); *In re O'Farrell,* 853 F.2d 894 (Fed. Cir. 1988); and *Amgen, Inc. v. Chugai Pharmaceutical Co.,* 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied,* 112 S.Ct. 169 (1991)). Given that none of the aforementioned references either alone or in combination would lead one to the present invention, Applicants request that the Examiner withdraw these rejections.

Moreover, not only is there no suggestion in any of the references to combine their disclosures, there is nothing to suggest any reasonable expectation of success, even if the cited references were combined. Even assuming, *arguendo*, that each of the references enable what they allegedly teach, there is no motivation to combine the references. As the Federal Circuit has recently reiterated, "virtually all inventions are combinations of old elements." Further, the Court noted that although an Examiner may often find every element of a claimed invention in the prior art, such a finding is insufficient to support a *prima facie* case of obviousness. To properly support a *prima facie* case of obviousness, the Examiner must show a motivation to combine the references. To this end, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet,* 47 USPQ2d 1453, 1458 (Fed. Cir. 1998). Further, when an Examiner relies on the skill in the art, the Examiner must "explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination." *Id.* As noted by the Federal Circuit, if merely "a rote invocation [of the skill in the art] could suffice to supply motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance." *Id.* In this regard, the Examiner has not pointed to the specific teaching which would lead one to combine the references in the manner suggested by the Examiner, without engaging in some form of impermissible hindsight reconstruction.

Moreover, even if one skilled in the art tried to combine the references, she would not be led to the claimed methods, as the references provide insufficient guidance and only support, at best, a very weak hindsight reconstruction of one aspect of the claimed invention. Accordingly, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness and, therefore, request that the Examiner withdraw the rejection.

Rejections under 35 U.S.C. §102(b)

The Examiner has alleged that claims 1 to 15, 16, 20 and 21 lack novelty under 35 U.S.C. § 102(b) as being allegedly anticipated by Zhang *et al.* or Gajdosova *et al.*, each in view of Levy *et al.* or Roue *et al.* Simply stated, neither Zhang *et al.* of Gajdosova *et al.* teach a composition for preventing, inhibiting, delaying onset of or otherwise ameliorating the effects of an autoimmune disease in a mammal. Certainly no other document teaches the use of *C. burnetii* or an extract thereof to treat IDDM. The Examiner admits this at page 10. It is stated that these documents "do not expressly teach [the] composition or the method for preventing, inhibiting or ameliorating an autoimmune disease in a mammal," The Examiner can only make this allegation by again indulging in hindsight reconstruction of the teaching of Levy *et al.* and Roue *et al.* However, even with these combinations, the prior art does not teach, suggest or even allude to the use of *C. burnetii* or an extract thereof to treat an autoimmune disease such as IDDM. Applicants respectfully submit that the claims stand novel in the light of the prior art, especially as proposed to be amended.

Objection to the claims

Claims 1 and 15 stand rejected do to their inclusion of the term "otherwise". This term has now been deleted and thus this objection has now been obviated.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC

William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:rap

Enclosures:

Postcard
Check
Fee Transmittal Form (+copy)
Petition for an Extension of Time (+ 2 copies)

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900 Fax: (206) 682-6031

L:\120081 - Aust. Nat'l University\403\Amendment 12-21-00.doc